K093527

Premarket Notification [510(k)] Summary
ARIA Radiation Oncology

The following information is provided following the format of 21 CFR 807.92.

Submitter's Name:

Varian Medical Systems, Inc.
3100 Hansen Way e-110
Palo Alto, CA 94304

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Date summary was prepared:02 November 2009

Proprietary Name:

ARIA Radiation Oncology

Classification Name:

Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: IYE, KPQ

Common/Usual Name:

Image Database

Predicate Devices:

Vision (with Off-Line Review), K062391
VelocityAIS (VelocityAI), K081076
IKOEngelo, K083591

Device Description:

ARIA Radiation Oncology is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatments planning, simulation, and plan verification and treatment. ARIA Radiation Oncology also stores the treatment histories including dose delivered to defined sites, and provides tools to verify performed treatments. ARIA Radiation Oncology is designed to assist the radiation therapy staff to prepare and approve treatment plans, and to perform quality assurance of the treatments, i.e., to follow-up the delivered treatments and dose to defined sites. The preparation tasks include image acquisition, viewing and manipulation, treatment plan definition, manipulation and scheduling.

ARIA Radiation Oncology (K042956) has been modified to introduce a new component called MIRS (Multimodality Image Registration and Segmentation). MIRS provides components to perform various types of image registration and segmentation to facilitate and support the clinical goals of image guidance and adaptation including: multimodality image review capabilities, deformable and rigid multimodality image, structure segmentation and approval and structure propagation between registered images.

ARIA Radiation Oncology is based on the client-server architecture, and thus all ARIA Radiation Oncology clients/workstations load data from

and store data to the common database. The database server provides data storage for other software products developed by Varian Medical Systems, Inc. (e.g., Eclipse, Acuity, PortalVision, and VARiSVision/ARIA).

Statement of Indications for Use: The ARIA Radiation Oncology product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment. ARIA Radiation Oncology also stores the treatment histories including dose delivered to defined sites and provides tools to verify performed treatments.

Technological Characteristics: Refer to the Substantial Equivalence Comparison Chart in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vy Tran
Vice President, Corporate Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

DEC 15 2009

Re: K093527
Trade/Device Name: ARIA Radiation Oncology with MIRS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE and MUJ
Dated: November 2, 2009
Received: November 16, 2009

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093527

Device Name: ARIA Radiation Oncology with MIRS

Indications for Use:

The ARIA Radiation Oncology product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment. ARIA Radiation Oncology also stores the treatment histories including dose delivered to defined sites and provides tools to verify performed treatments. ARIA also includes optional tools to manage the oncology department's clinical and business information.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
X		

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K093527